DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of the Clinical Director
National Institute of Child Health
and Human Development
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Bethesda, Maryland 20892-1832
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MEMORANDUM

DATE: June 26, 2008

TO: **Peter Scheidt, M.D., MPH**

FROM: Gilman Grave, MD

Through: Stephen G. Kaler, MD MPH
Clinical Director, NICHD

SUBJECT: Disposition from 06/25/08 NICHD Institutional Review Board Meeting

Below please find the disposition concerning the review of your protocol considered this week by the IRB. Thank you very much for submitting this interesting study.

NEW PROTOCOL

National Children's Study (The findings of the National Academy of Science Review, and the response to those findings.)
Principal Investigator: Peter Scheidt
Protocol Title: The National Children's Study – Pilot protocol.
Protocol number: New Application

Discussion and Disposition: The Board was favorably inclined in its consideration of the National Children's Study. However, it was understood that the final protocol and consent procedures were not yet finalized. Therefore, the Board agreed to table consideration of the protocol pending receipt of the updated protocol, consent form and the script for the consent video. The vote was 6 in favor, 1 opposed (the member preferred to defer consideration of the protocol without a formal vote).

Recommendations:

1. Provide updated protocol, consent form and script of consent video. Highlight changes
2. Provide list of DSMB members (including affiliations) for IRB review and

approval.

3. Provide a list of ongoing study working group members and affiliations
4. Provide an update to the IRB on at least a biannual basis.
5. Provide a plan for addressing health disparities noted in the IOM Report.
6. Provide a summary of the public comments received on the protocol.

THIS PROTOCOL EXPIRES JUNE 24, 2009

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RESEARCH CORPORATION

MEMORANDUM

TO: Elaine Eaker and Paul Hurwitz January 29, 2008

FROM: Kerry Levin
Acting Chair, Institutional Review Board

SUBJECT: IRB Review and Approval
National Children Study
Contract No. HHSN275200503395C
Project 8208
FWA5551

On January 8, 2008, the Westat Institutional Review Board (IRB) conducted its review of the following: **National Children's Study (NCS)**, Contract No. HHSN275200503395C, Project 8208. This review covers all procedures before and during the mother's pregnancy through the birth visit and the one month visit. Data collection activities with the mother, father and child after the one month visit will be presented and addressed at a subsequent IRB meeting. Westat's IRB reviews all studies involving human research before activities may begin under 45 CFR pt 46.

Due to the complexity of the study, project staff organized several informational steps to help familiarize the Board with the goals and objectives of the study prior to a voting decision. First, an informational session during the December 11th IRB meeting was held. During this meeting, project staff provided the Board with an overview of the project and presented a sample of the video consent process. Following this session, the IRB Board Chair circulated a series of questions from Board members to project staff. The final review of study materials and procedures took place during the January Board meeting which was also included a discussion of the answers provided to all of the questions and requests for further clarification regarding answers to some questions.

Following the January Board meeting, additional information was submitted by the NCS project staff to supplement answers to questions which had been submitted previously. These answers now appear in the final record and are included as an attachment to the study protocol. Some of the answers will require modification to the study protocol at a future time. It is anticipated that a copy of the revised protocol reflecting the answers to questions will be sent to this IRB for the record.

Lastly, even if the protocol does not change, if Westat's role with regard to data collection should change, those aspects of the study must be reviewed by the Westat IRB.

The Board determined that NCS presents no greater than minimal risk to the pregnant woman and their unborn children. It was also determined that the number of ultrasounds being conducted does not place the women or child at increased risk, based on documentation provided to the Board.

Because this study presents no greater than minimal risk, the Board waives the requirement for the father's consent for the child or unborn fetus [45 CFR 46.116 of Subpart A and 46.408 (b)]. The father however, will be required to provide written consent for his own participation in the study. In addition, a waiver for permission from both parents has been granted for emancipated pregnant minors as long as it does not conflict with local jurisdiction requirements. Each Study Center will be responsible for adherence to their local jurisdictional requirements regarding the consent and enrollment of pregnant minors. The Coordinating Center will prepare procedures to be used when the pregnant minor is legally allowed to provide consent, and when she is not, and the Study Centers will be required to adhere to their local laws.

Based upon this approval, the project must submit a Certificate of Confidentiality to the IRB as soon as it is received; no reference to the Certificate may be made to the women whose consent for enrollment is sought until the Certificate is obtained.

It is understood that no data collection will begin until approval of the study by the NICHD IRB. In addition, no data collection will begin at any study center site until the approval of the study, including all activities of the study center and their subcontractor or organizations, by that Center's IRB. It is anticipated that the NICHD agency IRB will serve as the central NCS IRB to review any protocol changes from the package approved here by the Westat IRB. Any such approvals of changes made by the NICHD IRB will be transmitted to the Westat IRB for our records and use in oversight of Westat's Coordinating Center activities.

In accordance with 45 CFR 46, the Board unanimously approved this study for the phases submitted, which includes procedures before and during the pregnancy of the mother, up to the birth of the child.

You are obligated to submit the study for an annual review on or before January 29, 2009. In the interim, you are responsible for notifying the Office of Research Administration as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board

WESTAT
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MEMORANDUM

TO: Elaine Eaker and Paul Hurwitz February 11, 2008

FROM: Kerry Levin
Kerry Levin
Acting Chair, Institutional Review Board

SUBJECT: ADDENDUM to approval letter dated 01-29-08 (CORRECTED)
National Children Study
Contract No. HHSN275200503395C
Project 8208
FWA5551

On January 29, 2008, the Westat Institutional Review Board (IRB) assigned full approval of the following: **National Children's Study (NCS)**, Contract No. HHSN275200503395C, Project 8208. The approval covered all procedures before and during the mother's pregnancy through the birth visit and the one month visit. Data collection activities with the mother, father and child after the one month visit will be presented and addressed at a subsequent IRB meeting. Westat's IRB reviews all studies involving human research before activities may begin under 45 CFR pt 46.

Because this study presents no greater than minimal risk, requests for five waivers of informed consent were granted by the board. The first three requests described below are waivers for *documentation* of informed consent. The remaining two requests are waivers to allow signed informed consent from only one parent or guardian since the IRB determined that permission of one parent was sufficient. However, while discussed at the board meeting, explicit descriptions of each waiver were inadvertently omitted from the approval letter. Therefore, each waiver is listed below:

1. A waiver of the requirement for documentation of informed consent (obtaining a signed consent form) for the enumeration stage. This step is designed to locate households containing potentially eligible women for the Study. IRB regulations permit waiver of documentation of informed consent when the research presents no more than minimal risk [45 CFR pt. 46.116 (d) 46.117 (c) (2)].

2. A waiver of the requirement for documentation of informed consent (obtaining a signed consent form) for the screening stage. This step is only designed to determine the eligibility of women for the study. The vast majority of women will not be eligible for the study. IRB regulations permit waiver of documentation of informed consent when the research presents no more than minimal risk [45 CFR pt. 46. 116 (d) 46.117 (c) (2)].

3. A waiver of the requirement to obtain a signed consent form for each specific study visit after enrollment. The project will obtain signed informed consent at enrollment, using

either the video or the paper form, for eligible participants who choose to join the study. IRB regulations permit waiver of documentation of informed consent when the research presents no more than minimal risk and participants are provided with written information regarding the research[45 CFR pt. 46. 116 (d) 46.117 (c)(2)].

4. A waiver for both parents of the unborn child to sign the consent form for enrollment of pregnant women and their unborn children into the study. The Board waives the requirement for the father's consent for the child or unborn fetus [45 CFR 46.116 of Subpart A and 46.408 (b)]. The father however, will be required to provide written consent for his own participation in the study.

5. A waiver for both parents of pregnant minors to sign the consent form for enrollment of pregnant minors into the study as long as it does not conflict with local jurisdiction requirements. *45 CFR Part 46, Subpart D provides for "Additional Protections for Children Involved as Subjects of Research." The requirement for parental permission may be inappropriate in some cases. Examples include research involving older adolescents who, under applicable law, may consent on their own behalf*. The Coordinating Center will prepare procedures to be used when the pregnant minor is legally allowed to provide consent, and when she is not. Each Study Center will be responsible for adherence to their local jurisdictional requirements regarding the consent and enrollment of the pregnant minor.

Note: All information included in the approval letter date January 29th, 2008 remains unchanged.

cc: Institutional Review Board